

GOVERNMENT OF TELANGANA  
ABSTRACT

Health Medical & Family Welfare Department – Drugs Control Administration, Hyderabad- Withdrawal of Prosecution of the case filed against M/s Hyderabad Eye Institute (L.V.Prasad Hospital), Road No.2, Banjara Hills (Under trust eye institute), before the Hon'ble III Additional Chief Metropolitan Magistrate (ACMM) Court Nampally by the Drugs Control Administration Department – Orders – Issued.

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HEALTH, MEDICAL & FAMILY WELFARE (C2) DEPARTMENT

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G.O.Rt. No.480

Dated.25/08/2018

Read the following:

1. From the Joint Director & Licensing and Controlling Authority, DCA, Hyd, Lr. Rc. No. 7694/JD/DCA/2016, Dt. 12/7/2016.
2. From the Joint Director & Licensing and Controlling Authority, DCA, Hyd, Lr. Rc. No. 0746/DCA/2017, Dt. 27/9/2017.

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ORDER:

The Joint Director, Drugs Control Administration, Hyderabad in his letter second read above, has stated that the Drugs Inspector, Ameerpet zone has seized the documents pertaining to purchase and utilisation of Avastin in eye patients, copy of case sheets, copy of Label and inner leaflet of Avastin injection (100mg/4ml) and other documents for using Avastin injection in eye patients against the prescription of ophthalmologist under the cover of a Panchanama. A receipt in Form -16, dt. 16.06.2016 duly mentioning the details of the seized drugs was issued to the firm under acknowledgment. A notice was served to the firm to submit reply. In reply to the letter addressed, the firm has replied that the Drug Controller General of India (DCGI) has withdrawn the alert notice given dt. 21.01.2016 vide their reference No. 12-52/2004 on dt. 11.03.2016 and also submitted that the Drug Controller General of India has accepted the Guidelines submitted by the Vitreo Retinal Society of India (VRSI) Sub-committee and accepted the off label use of Avastin injection in Ophthalmological surgeries, used by skilled ophthalmologist.

2. The Joint Director, Drugs Control Administration, Hyderabad has further stated that a complaint was submitted to the Sr. Assistant Public Prosecutor, III Additional Chief Metropolitan Magistrate (ACMM) against M/s. Hyderabad Eye Institute. The Senior Assistant Public Prosecutor opined that the case is "Not Fit Case in Point of Law" as the Drug Controller General of India has accepted the guidelines prepared by Vitreo Retinal Society of India sub-committee as mentioned in file F.No. 12-52/2004 on dt. 11-3-2016, which is alert notice withdrawal notice issued by Drug Controller General of India. The off label usage can be done with skilled ophthalmologist following guidelines prepared by Vitreo Retinal Society of India Sub-committee. M/s Hyderabad Eye Institute (Under trust eye institute) has mentioned the same in their reply and submitted proofs as they were carrying the same procedures as mentioned in the guidelines prepared by Vitreo Retinal Society of India along with consent forms should be taken from patients as per approved guidelines option 3 (c) (1) i.e., Intravitreal injection guidelines, and also submitted their National Accreditation Board for Hospitals & Healthcare Providers (NABH) accreditation certificate. The Joint Director, Drugs Control Administration, Hyderabad has therefore requested the Government to give necessary directions for closure of prosecution as per the opinion of the Senior Assistant Public Prosecutor, III Additional Chief Metropolitan Magistrate (ACMM) Court, Nampally, Hyderabad.

3. Government, after careful examination of the matter, hereby decided to withdraw the prosecution against the accused as mentioned in this case and instruct the Joint Director, O/o Drugs Control Administration, Hyderabad to request the Senior Assistant Public Prosecutor, III Additional Chief Metropolitan Magistrate (ACMM) Court, Nampally, Hyderabad to take necessary action for withdrawal of prosecution against M/s Hyderabad Eye Institute (L.V.Prasad Hospital), Road No.2, Banjara Hills (Under trust eye institute) before the Hon'ble III Additional Chief Metropolitan Magistrate (ACMM) Court, Nampally by the Drugs Administration Department., under intimation to the Government.

[P.T.O.]

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4. The Director, Drugs Control Administration, Hyderabad shall take necessary action accordingly.

(BY ORDER AND IN THE NAME OF THE GOVERNOR OF TELANGANA)

A. SANTHI KUMARI  
PRINCIPAL SECRETARY TO GOVERNMENT

To

The Director, Drugs Control Administration, Hyderabad.

Copy to

The Chairman, L.V. Prasad Eye Institute through DCA, Hyderabad.

The Senior Assistant Public Prosecutor, III Additional Chief Metropolitan  
Magistrate (ACMM) Court, Nampally, Hyderabad

The Law (C) Department, T.S., Secretariat, Hyderabad

SF/SC

// FORWARDED :: BY ORDER //

SECTION OFFICER